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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,317	03/12/2004	Hon-Wah Man	501872-999097	5806
20582	7590	03/09/2005	EXAMINER	
JONES DAY 51 Louisiana Aveue, N.W WASHINGTON, DC 20001-2113			LEE, SUSANNAH E	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,317

Applicant(s)

MAN ET AL.

Examiner

Susannah Lee

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 8, 9, 10, 15, 17, -21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-7, 11-14 and 16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

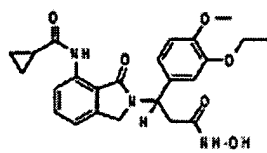
Claims 1-21 are pending in the instant application. Claims 22-45 have been canceled by preliminary amendment filed on 03/12/2004.

Priority

This application claims benefit of Application No. 60/454,155 filed on 03/12/2003. The application names an inventor or inventors named in the prior application.

Response to Election/Restriction

Applicant's election with traverse of Group I in the reply filed on 01/31/2005 is acknowledged. Specially, the election of species of the compound of claim 1,



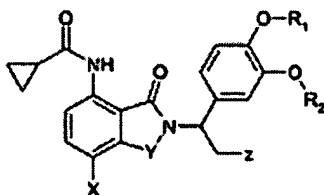
, cyclopropanecarboxylic acid {2-[1-(3-ethoxy-4-methoxy-phenyl)-2-hydroxycarbamoyl-ethyl]-3-oxo-2,3-dihydro-1H-isindol-4-yl}-amide, is acknowledged.

The traversal is on the ground that claims 5-7, 11-12, and 13-14, to the extent that they depend on claim 1 should also be included in Group I. Examiner agrees and will include these claims to the extent that they depend on claim 1.

The requirement is still deemed proper and is therefore made FINAL.

Scope of Elected Subject Matter

The scope of the invention of the elected subject matter is as follows:



Compounds of formula (I),

, depicted in claim 1, wherein:

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Y is $-\text{C}(\text{O})-$, $-\text{CH}_2-$, $-\text{CH}_2\text{C}(\text{O})-$ or $-\text{SO}_2-$;

X is H;

Z is (C0-4-alkyl)- $\text{C}(\text{O})\text{R}_3$, C1-4-alkyl, (C0-4-alkyl)-OH, (C1-4-alkyl)-O-(C1-4-alkyl), (C1-4-alkyl)- SO_2 (C1-4-alkyl), (C0-4-alkyl)-SO(C1-4-alkyl), (C0-4-alkyl)- NH_2 , (C0-4-alkyl)-N(C1-8-alkyl) $_2$, (C0-4-alkyl)-N(H)(OH), or CH_2NSO_2 -(C1-4-alkyl);

R1 and R2 are independently C1-8-alkyl, cycloalkyl, or (C1-4-alkyl)-cycloalkyl;

R3 is NR_4R_5 , OH, or O-(C1-8-alkyl);

R4 is H;

R5 is $-\text{OH}$, or $-\text{O}-\text{C}(\text{O})\text{R}_6$;

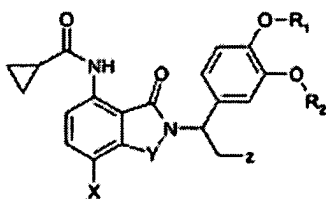
R6 is C1-8-alkyl, amino-(C1-8-alkyl), (C1-8-alkyl)-(C3-6-cycloalkyl), C3-6-cycloalkyl, phenyl, benzyl, or aryl;

Or a pharmaceutically acceptable salt or solvate thereof.

Claims 1 (in part), 2, 5-7 (in part), 11-14 (in part), and 16 are the elected subject matter.

Scope of the Withdrawn Subject Matter

The scope of the withdrawn subject matter is as follows:



Compounds of formula (I), , depicted in claim 1, wherein:

Z is (C0-4-alkyl)-dichloropyridine.

As a result of the election and the corresponding scope of the invention identified supra, where Z is (C0-4-alkyl)-dichloropyridine is withdrawn because pyridine is chemically recognized to differ in structure and function as the core compound. The core compound can be

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pyrrolidine or isothiazolidine. This recognized chemical diversity of the functional group can be seen by the various classifications in the U.S. Classification System. For instance, pyridine is in various subclasses of class 546 and the core compounds, pyrrolidine and isothiazolidine, are in various subclasses of class 548. Therefore the subject matter which is withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly.

Claims 1 (in part), 3-4, 5-7 (in part), 8-10, 11-14 (in part), 15, 16 (in part), 17-21 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Obviousness Double Patenting

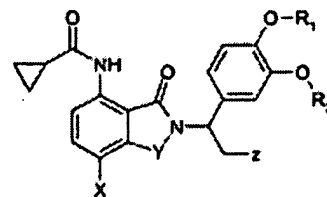
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

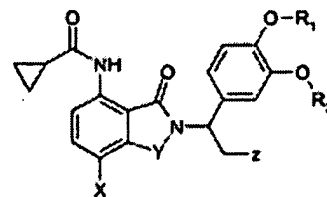
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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5-7, 11-14, and 16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-19 of co-pending U.S. Application No. 10/748,085. This is a *provisional* double patenting rejection since the conflicting claims have not yet been patented.

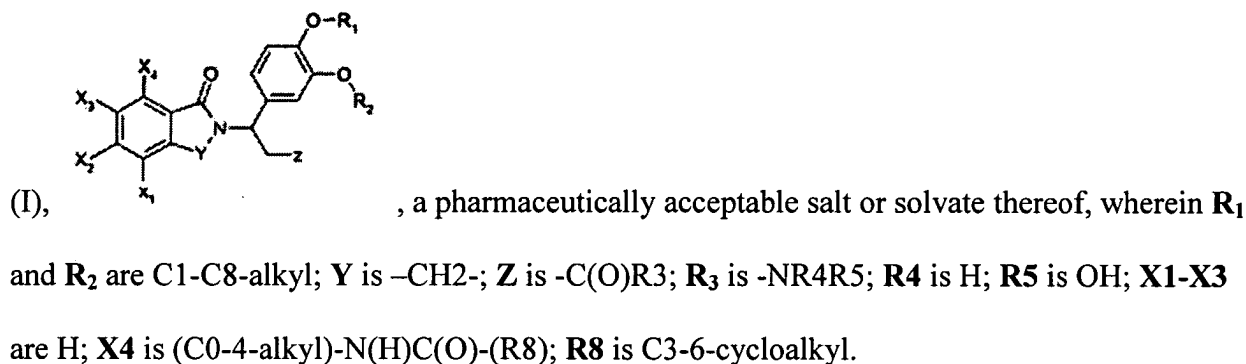


Instant claim 1 discloses a compound of the formula (I), , a pharmaceutically acceptable salt or solvate thereof, wherein **R**₁ and **R**₂ are C1-C8-alkyl; **Y** is -CH₂-; **X** is H; **Z** is (C0-4-alkyl)-C(O)**R**₃; **R**₃ is NR₄**R**₅; **R**₄ is H; **R**₅ is OH. The prior art of U.S. Application Num. 10/748,085 teaches this compound.

Determination of the scope and content of the prior art (MPEP § 2141.01)

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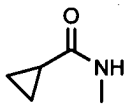
The prior art of U.S. Application Num. 10/748,085 teaches a compound of the formula



Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art and the instantly claimed compounds is that the prior art gives broader definitions than the instantly claimed compounds. Although the claims are not identical they are not patentably distinct from each other.

The difference between the prior art and the instant claims is that in the prior art **X₄** can be halogen, nitro, NH₂, CF₃, C1-6-alkyl, (C0-4-alkyl)-(C3-6-cycloalkyl), (C0-4-alkyl)-NR₇R₈, (C0-4-alkyl)-N(H)C(O)-(R₈), (C0-4-alkyl)-N(H)C(O)N(R₇R₈), (C0-4-alkyl)-N(H)C(O)O(R₇R₈), (C0-4-alkyl)-OR₈, (C0-4-alkyl)-imidazolyl, (C0-4-alkyl)-pyrrolyl, (C0-4-alkyl)-oxadiazolyl, or (C0-4-alkyl)-triazolyl or X₃ and X₄ are taken together with the atoms that join them to form a cycloalkyl or heterocycloalkyl ring of 3, 4, 5, 6, or 7 atoms, while in the

instant claims it can only be  , a cyclopropanecarboxamide group, (C0-alkyl)-N(H)C(O)-(R₈), where R₈ is C3-cycloalkyl, which the prior art teaches.

The difference between the prior art and the instant claims is that in the prior art **X₁-X₃** can be halogen, nitro, NH₂, CF₃, C1-6-alkyl, (C0-4-alkyl)-(C3-6-cycloalkyl), (C0-4-alkyl)-NR₇R₈, (C0-4-alkyl)-N(H)C(O)-(R₈), (C0-4-alkyl)-N(H)C(O)N(R₇R₈), (C0-4-alkyl)-

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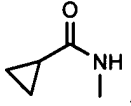
N(H)C(O)O(R7R8), (C0-4-alkyl)-OR8, (C0-4-alkyl)-imidazolyl, (C0-4-alkyl)-pyrrolyl, (C0-4-alkyl)-oxadiazolyl, or (C0-4-alkyl)-traizolyl or X3 and X4 are taken together with the atoms that join them to form a cycloalkyl or heterocycloalkyl ring of 3, 4, 5, 6, or 7 atoms, while in the instant claims it can only be hydrogen, which the prior art teaches.

There is a significant overlap in **Z** between the prior art and the instantly application.

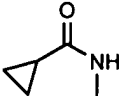
The commonalities include the preferred species, a $\text{—}\overset{\text{O}}{\parallel}\text{C—}\overset{\text{H}}{\text{N}}\text{—OH}$ group.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

Although the conflicting claims are not identical, they are not patentably distinct from

each other because the prior art teaches the instantly claimed compound where X4 is ,

X1, X2, and X3 are hydrogen, and Z is $\text{—}\overset{\text{O}}{\parallel}\text{C—}\overset{\text{H}}{\text{N}}\text{—OH}$. In claim 3 of the prior art, it teaches that

the preferred species of X4 is , a cyclopropanecarboxamide group, (C0-4-alkyl)-

N(H)C(O)-(R8). Claim 15 teaches several species that have a cyclopropanecarboxamide group and where X1, X2 and X3 are hydrogen (See Claim 15, p. 91, lines 9-14, 31-32; p. 92, lines 1-2, 12-17). In claim 11 it teaches that the preferred species is where three of X1, X2, X3 and X4 are

H. In claim 15, the preferred species, where Z is $\text{—}\overset{\text{O}}{\parallel}\text{C—}\overset{\text{H}}{\text{N}}\text{—OH}$, are taught (See claim 15, p. 90, lines 8, 10, 12; p. 91, lines 3, 5, 15-27).

In addition, Application No. 10/748,085, which discloses specific compounds in any pharmaceutically acceptable salt, solvate, hydrate, stereoisomer, clathrate or prodrug thereof (see claims 1-15) are more specific embodiments that anticipate the compounds and salts as instantly

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claimed and one skilled in the art would have been motivated to make enantiomers, diastereomers, or tautomers of the claimed compounds and salts when faced with the prior Application No. 10/748,085.

Therefore, one skilled in the art would have found this variation obvious when faced with U.S. Application No. 10/748,085 because both compounds are used for the same pharmacological use so one skilled in the art would expect similar properties and results.

Conclusion

Claims 1, 2, 5-7, 11-14, and 16 are rejected under the provisional double patenting rejection as being unpatentable over Application Number 10/748,085 at this point in the examination process.

Telephone Inquiry

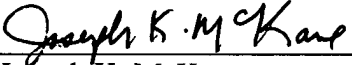
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Lee whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Lee
Patent Examiner, AU 1626



Joseph K. McKane
Supervisory Patent Examiner
AU 1626
Date: 03/04/05